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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/350,466 07/09/99 SPITLER

M CHEMM-101XX

EXAMINER

IM22/0705

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CROSS, I

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/350,466

Applicant(s)

SPITLER ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 21-42 is/are pending in the application.
- 4a) Of the above claim(s) 25,30-33 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 21-27,34 and 37-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 and 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restriction

- I. Claims 21-29, 34 and 37-42, drawn to an analytical detection element, classified in class 436, subclass 169.
- II. Claims 30-33, drawn to a multi-layer analytical detection element, classified in class 436, subclass 170.
- III. Claim 35, drawn to a container, classified in class 422, subclass 58.
- IV. Claim 36, drawn to a container, classified in class 422, subclass 58.

The inventions are distinct, each from the other because of the following reasons:

- 1. Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups I and II are directed to analytical devices having different structures. The inventions of groups III and IV are directed to two containers having different structure. Regarding groups I and II, the two analytical devices would presumably function differently. The same applies to the two different containers of groups III and IV.
- 2. Because these inventions are distinct for the reasons given above and the search required for Groups II, III and IV is not required for Group I, restriction for examination purposes as indicated is proper.

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3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Holly Heine on May 17, 2001 a provisional election was made without traverse to prosecute the invention of group I, claims 21-29, 34 and 37-42. Affirmation of this election must be made by applicant in replying to this Office action. Claims 30-33, 35 and 36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The use of several trademarks has been noted in this application (pages 9, 16, 18-20 and 22-31). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: Figures 2c and 2d, described at page 13, line 17. Correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 21-29 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 38 contain the phrase "high boiling plasticizer/solvent". The phrase "high boiling" is relative and thus indefinite.

Claims 21 and 38 also contain the phrase "a second region for sequestering radiant energy detectable material displaced from or produced by material displaced from said solid prior to detection of said radiant energy detectable material". The language used in this limitation is unclear. It is suggested that Applicants use language such as "a second region for sequestering radiant energy detectable material displaced from said solid prior to the radiant energy detectable material being detected".

Claim 27 contains the phrase "multiple small pieces". The term "small" is relative and thus indefinite.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 21, 23, 26-29, 34, 37, 38 and 40-42 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,042,335 to Clement (hereinafter Clement '335).

Applicants' claimed invention is directed to an analytical detection element and method of detecting analytes using the detection element. The detection element comprises a solid, a radiant energy detectable material absorbed on the solid, a region for sequestering radiant energy detectable material displaced from the solid and a plasticizer/solvent.

Clement '335 teaches an integral analysis element in multi-layer form which may be configured in the form of smaller chips (col. 19, lines 7-11). The analytical element of Clement '335 comprises a first reagent layer constructed of a fibrous matrix and having absorbed thereon a composition that is interactive in the presence of an analyte to provide a diffusible, detectable species. The reagent layer can be composed of a solution or dispersion of one or more test reagents in a binder (col. 19, lines 28-31). The analytical element also contains a registration layer that is permeable to the detectable species allowing the detectable species from the reagent layer to diffuse into it (the registration layer) and be detected. See col. 5, lines 46-54, col. 8, lines 1-7 and lines 56-68. A radiation blocking layer, such as a reflecting layer and/or an opaque

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layer, may be present to facilitate result detection (col. 11, lines 41-62). In example 1 of the reference, an analytical element is illustrated having a registration layer, a reflective radiation blocking layer, and a reagent layer containing a dye precursor (4-aminoantipyrine) and a plasticizer (glycerine). The example discusses analyzing glucose solutions whereby glucose solutions are added drop-wise to the analytical element. In layer 3 (the reagent layer), a series of reactions take place and produce a dye which diffuses out of the reagent layer, through the radiation blocking layer and into the registration layer where the dye can be detected.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102, in view of the teachings of Clement '335.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 22, 24, 25, 34 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clement '335 in view of US Patent 4,421,719 to Burleigh (hereinafter Burleigh '719).

The disclosure of Clement '335 is given above.

Clement '335 does not disclose the use of solids such as those recited in claims 22 and 39, having radiant energy detectable materials absorbed thereon. Clements '335 also does not disclose a single layer analytical element.

Burleigh '719 teaches colorimetric indicators comprising an indicator substance coated on a backing. The indicator, which may be a dye, dye precursor, or bleachable dye, reacts with a selected substance and changes color to denote the presence of the selected substance. The indicator substance is absorbed onto an absorbent carrier such as alumina, silica or carbon and is affixed to a suitable substrate (backing) via a clay mineral binder.

It would have been obvious to one of ordinary skill in the art to use such carrier coated indicators, as disclosed by Burleigh '719, since the porosity of carriers like alumina, silica, and carbon allows the indicator substance as well as toxic substances to be absorbed thereon. As taught by Burleigh '719, at col. 3, lines 30-33, high surface area materials such as these serve as a medium for toxic substance absorbency, thereby allowing a more accurate detection of such.

With respect to claims 24 and 25, it would have been obvious to one of ordinary skill in the art, at the time of Applicants' invention, to construct the analytical device in any manner most convenient and efficient for its use. Single layer analytical elements (mostly test strips having non-discrete layers) are conventionally used in the art where selective migration of materials must be conducted. It does not appear that the use of a single layer provide any advantage over multiple layered elements.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Clement '335 in view Burleigh '719.

Citation of Relevant Prior Art

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 4,166,093 to Smith-Lewis et al discloses an analytical element containing a detectable species migration-inhibiting layer between a radiation blocking layer and a reagent layer.


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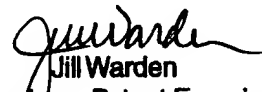
US Patent 5,122,451 to Tanaka et al discloses a multi-layer analytical element comprising a reagent layer, light reflecting layer, and spreading layer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC 
June 26, 2001


Jill Warden
Supervisory Patent Examiner
Technology Center 1700